ENSURING TREATMENT ADHERENCE & COMPLETION and PROVIDING DIRECTLY OBSERVED THERAPY - DOT

FOR PERSONS WITH SUSPECT OR ACTIVE TUBERCULOSIS DISEASE OR LATENT TUBERCULOSIS INFECTION (LTBI)

GUIDELINE for ESTABLISHING EFFECTIVE
POLICIES, PROCEDURES AND PRACTICES

This guideline has been developed by the Wisconsin Department of Health and Family Services as a tool to assist local health departments in updating or developing policies, procedures and practices for the care of clients with tuberculosis. It serves as a model and needs to be adapted according to each local health department's needs. Items that provide additional information, education or reference are in italics or are otherwise highlighted, such as in boxes. These portions are included for use during the adaptation process, are not written in policy and procedure language and are not required to be in the local health department's final policy and procedure documents.

Because it is not possible for any guideline to address all potential situations for individuals, clinical judgement must always be exercised. All other legal requirements must be followed to ensure "due process" and all laws pertaining to minors and/or persons with guardians are to be followed when implementing this guideline.

When federal regulations, state statutes, administrative codes, CDC endorsed guidelines or standards of practice pertaining to tuberculosis are revised, the Division of Public Health will notify local health departments of the availability of these resources. Local health departments need to update their policies, procedures and practices accordingly to remain consistent with ongoing changes in legal requirements and tuberculosis care, for both the health of the affected individuals and the health of the public.

GUIDELINE for POLICY DEVELOPMENT

I. Terms and Definitions
II. Purpose
III. Persons Affected/Responsible
IV. Suggested Policy Language
V. Legal Authority
VI. References

GUIDELINE for PROCEDURE DEVELOPMENT

I. Terms and Definitions
II. Purpose
III. Persons Affected/Responsible
IV. Suggested Procedure Language
V. References

APPENDIX - TABLE OF CONTENTS & RESOURCES

GUIDELINE for ESTABLISHING EFFECTIVE PRACTICE	Reviewed/Revised:
Ensuring Treatment Adherence & Completion & Providing DOT for Persons with Suspect or Active Tuberculosis Disease or Latent Tuberculosis Infection (LTBI)	Signatures & Dates: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
_____ Health Department Original Effective Date _____ Approved by _____	

GUIDELINE for POLICY DEVELOPMENT

I. Terms and Definitions:

Adherence – Consistently maintaining a prescribed medication regimen as a result of a cooperative partnership in which the client participates fully and is supported by the provider, the two parties having shared responsibilities for treatment outcomes.

Culture Confirmed Tuberculosis – Tuberculosis disease that has been confirmed by culture-positive identification on a clinical specimen.

Directly Observed Therapy (DOT) – The ingestion of prescribed anti-tuberculosis medication that is observed by a health care worker or other responsible person acting under the authority of the local health department.

Drug Resistant TB – TB from a strain of *M. tuberculosis* that has the ability to grow and multiply in the presence of a drug that is usually effective against TB. Types of drug resistance include:

- **Acquired resistance –** A phenomenon in which exposure to a single drug, due to irregular drug supply, poor drug quality, inappropriate prescription and/or poor adherence to treatment suppresses the growth of bacilli susceptible to that drug but permits the multiplication of drug-resistant organisms.

- **Multi-drug resistance** – A condition in which the organisms in the body are resistant to at least isoniazid and rifampin.

- **Primary resistance** – Subsequent transmission of bacilli that are drug resistant to other persons that may lead to disease which is drug resistant from the outset, also known as transmitted resistance.

- **Transmitted resistance** – TB drug resistance that occurs when a strain of TB already resistant to one or more anti-TB drugs is transmitted to a new case and results in resistance to the same number and types of drugs as in the source case; also known as primary resistance.

Enablers – Things that help a person overcome other pressing needs in their lives that compete with treatment adherence or DOT, thus promoting and supporting completion of treatment.

Extrapulmonary tuberculosis – Tuberculosis in any part of the body other than the lungs.

High prevalence groups – Groups of people who are more likely to be exposed to and infected with TB, including close contacts of people with infectious TB, people born in areas of the world where tuberculosis is common, low-income groups with poor access to health care, elderly people, people who live or work in certain facilities, people who inject drugs and people in other locally identified groups.

High-risk populations – Certain demographic groups who are at a greater risk than the general U.S. public to contract a particular disease. In the case of TB, these groups include individuals who are economically disadvantaged; co-infected with HIV; persons from countries where TB is endemic; members of a racial or ethnic minority group; substance abusers; homeless persons, migrant workers; incarcerated; very young or advanced in age and those with medical risk factors for tuberculosis.

High-risk tuberculosis – An infection with tuberculosis that is highly likely to progress to active disease and may easily become infectious if it remains untreated.

Immunocompetent – Capable of producing normal or adequate immune responses.

Immunosuppression – The suppression of natural human responses to infection as caused by disease, malnutrition, or medical treatment involving drugs or irradiation.

Incentives – Rewards that are given to clients either to encourage them to take their medications or to adhere to regular clinic or field visits for DOT.

Infection – The condition in which organisms capable of causing disease enter the body and elicit a response from the host's immune system. TB infection may or may not lead to active TB disease, however persons with infection remain at life-long risk of developing active disease if their infection goes untreated. Also known as latent tuberculosis infection (LTBI).

Infectious tuberculosis – Tuberculosis disease of the respiratory tract, capable of producing infection or disease in others as demonstrated by the presence of acid-fast bacilli in the sputum or bronchial secretions or by chest radiograph and clinical findings.

Intermittent therapy – Medications administered two or three times per week, rather than daily. All intermittent therapy must be directly observed by a health care worker or other responsible person acting under supervision.

Interpretation – the oral restating in one language of what has been said in another language. Interpreted information should accurately convey the tone, level and meaning of the information given in the original language. (National Association of Judiciary Interpreters and Translators)

Laryngeal tuberculosis – Tuberculosis of the larynx; often considered more infectious than pulmonary TB; organisms are generally exhaled by the person with the disease.

Latent TB infection (LTBI) – Infection with *M. tuberculosis*, usually detected by a positive PPD skin test result, in a person who has no symptoms of active TB or radiographic evidence of active TB, and is not infectious. Tubercle bacilli are present in the body but the disease is not clinically active; same as TB infection.

Medicaid Tuberculosis-Related Benefit (MA TR Benefit) – A Medicaid benefit that covers TB clinical services for individuals meeting the financial eligibility requirements who are infected with tuberculosis or those who have active disease.

Relapse – Active TB that develops within the first two years after successful completion of therapy. In such cases of relapse, the organism often has a susceptibility pattern that is similar to that of the initial infection. The possibility of a new infection with *M. tuberculosis* should also be considered.

Suspect tuberculosis – An illness marked by symptoms such as prolonged cough, prolonged fever, hemoptysis; compatible radiographic or medical imaging findings; or laboratory tests that may be indicative of tuberculosis.

Symptomatic – Having symptoms that *may* indicate the presence of TB *or* another disease, such as cough, fever, night sweats, weight loss, hemoptysis, etc.

TB Case – A particular episode of clinically active TB. This is only used to refer to the disease itself, not the client with the disease. By law, cases of TB must be reported to the local health department as well as suspect tuberculosis as defined above.

Translation – the written conversion of written materials from one language to another.

Treatment failures – TB disease in clients whose disease does not respond to chemotherapy or in clients whose disease worsens after having improved initially. For a pulmonary tuberculosis case this is evidenced by a positive acid-fast sputum culture after 5 months of treatment. This can be the result of an inappropriate dosage or inadequate number of drugs, client nonadherence, malabsorption, or organism resistance.

II. Purpose:

The purpose of this policy is to ensure adherence to prescribed treatment regimens for persons with suspect or active tuberculosis disease or latent tuberculosis infection (LTBI). This is done by ensuring that persons affected by tuberculosis receive the appropriate care and management services, including directly observed therapy (DOT) as indicated to protect the health of the public and to eventually eliminate tuberculosis.

*"All TB control is local control." All TB prevention and control activities are the responsibility of the **local** health department. It is the health department's responsibility to ensure that adherence with treatment is maintained, treatment is completed and risk of transmission to others is eliminated. Directly observed therapy (DOT) is a standard of care in tuberculosis treatment and management. The local health department is responsible for ensuring that the care delivered and/or arranged for by the health department protect the health of the public. This guideline serves as an adjunct to help the local health department meet the standard of care for tuberculosis.*

III. Persons Affected/Responsible:

This policy will be carried out by _____ under the direction of
(List staff positions affected)
the health officer of the _____ health department.
City/County

IV. Suggested Policy Language:

The _____ Health Department will ensure that **all** clients are comprehensively assessed and evaluated and that they are ***considered*** for DOT. Supportive services and incentives/enablers that reduce barriers to adherence will be provided or arranged for by the health department to ensure completion of treatment and to protect the health of the public. The Health Department will ensure that all clients for whom DOT is indicated by CDC protocols, standards of practice or recommendations of the WI TB Program, will be provided with DOT.

"CDC and the American Thoracic Society recommend that DOT be considered for all clients because of the difficulty in predicting whether a client will be adherent."
Improving Client Adherence to Tuberculosis Treatment, CDC, 1994

The Health Department will prioritize the provision of all public health services for tuberculosis in their jurisdiction with emphasis on: first, the care of persons with suspect and active disease; second, persons who are close or high-risk contacts of persons with suspect or active disease; and third, those with latent tuberculosis infection (LTBI). The health department will evaluate data to determine the percentage of clients in their jurisdiction who complete therapy and will expand the use of measures to increase medication adherence, including increasing DOT if necessary, to meet established treatment completion goals and to protect the health of the public.

The Health Department may choose to support the use of unlicensed personnel or volunteers as determined by health department decision, as a valuable adjunct to assure medication adherence for persons affected by tuberculosis. If such persons are utilized, the health department and staff will adhere to statutes, rules and standards of practice for the implementation of such services.

The Health Department will utilize legal measures for persons who fail to adhere to prescribed medications and present a risk to the health of the public. When persons with tuberculosis refuse to adhere to prescribed medications and/or at any time present a risk to the health of the public, the health officer may issue an order requiring the person to receive DOT. Should it become necessary at any time, the health officer or the Department of Health and Family Services (DHFS) will obtain an order from the court to provide DOT. (*See Isolation Guideline for an adaptable sample of a typical health officer order. See this appendix for sample DOT Court Order*.)

If the person fails to comply with court ordered DOT, the person may be subject to isolation or confinement pursuant to s. 252.07(8) and (9), Wis. Stats., or to other and additional sanctions as the Court may determine. The Health Department will follow the policies and procedures for Isolation or Confinement as indicated.

V. Legal Authority:

The local health officer has authority under Wisconsin Statutes, Wis. Stats. ss. 252.07(8) & 252.07(9) and Wisconsin Administrative Code HFS 145.05 (1).

VI. References Used for State Guideline Development

[*The following references were used to develop the model state guideline. Any additional references used by the local health department should also be listed in the final policy and procedure document.*]

1. American Academy of Pediatrics. **Red Book 2000, Report of the Committee on Infectious Disease**, 25th Edition, 2000.

2. American Thoracic Society and Centers for Disease Control and Prevention. **Diagnostic Standards and Classification of Tuberculosis in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, April, 2000, 161:1376-1395.

3. American Thoracic Society. **Treatment of tuberculosis and tuberculosis infection in adults and children.** American Journal of Respiratory and Critical Care Medicine, 1994; 149: 1359-74.

4. Bartlett, E.E., Behavioral Diagnosis: A Practical Approach to Client Education, **Client Counseling and Health Education.** 1982; 4(1):29-35.

5. California Department of Health Services and California Tuberculosis Controllers Association Joint Guidelines. **Directly Observed Therapy Program Protocols in California**. 1997.

6. CDC Division of AIDS, STD and TB Laboratory Research, Tuberculosis/Mycobacteriology Branch, www.cdc.gov/ncidod/dastlr/TB/TBpublications.htm.

7. Centers for Disease Control and Prevention. **Core Curriculum on Tuberculosis: What the Clinician Should Know**. Fourth Edition, 2000.

8. Centers for Disease Control and Prevention. **Forging Partnerships to Eliminate Tuberculosis**. 1995.

9. Centers for Disease Control and Prevention. **Improving Client Adherence to Tuberculosis Treatment**. 1994.

10. Centers for Disease Control and Prevention. Morbidity & Mortality Weekly Report, Volume 44/No. RR-11. **Elements of a Treatment Plan for TB Clients**.

11. Centers for Disease Control and Prevention. **Self-Study Modules on Tuberculosis**. Modules 1-5, 1995. Modules 6-9, 2000.

12. Centers for Disease Control and Prevention. **Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**. MMWR April, 2000;49 (No. RR-6).

13. Division of Public Health, Bureau of Communicable Diseases. **EPINET, Wisconsin Disease Surveillance Manual** [*Updated periodically on the Health Alert Network (HAN).*]

14. Division of Tuberculosis Control, South Carolina Department of Health and Environmental Control, **Enablers and Incentives**, 1989.

15. National Tuberculosis Controllers Association. **Tuberculosis Nursing: A Comprehensive Guide to Client Care**, 1997.

16. New Jersey Medical School National Tuberculosis Center. **Tuberculosis Glossary**, 1995 & T**uberculosis School Nurse Handbook**, 1998.

17. North Carolina Division of Epidemiology, Department of Health and Human Services. **North Carolina Tuberculosis Policy Manual**. 1997.

18. Pickering, L.K., ed. **Tuberculosis**. In: 2000 Red Book: Report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2000, 593-613.

19. **TB Fact Sheet Series** found at http://www.dhfs.state.wi.us/dph_bcd/TB/Resources/TB_resources2.htm.

    Sputum Conversion during TB Treatment, (POH 7131)
    Rifater and Rifamate in the Treatment of TB (POH 7133)
    Tuberculin Skin Testing for Suspected TB (POH 7134)
    The Importance of Rifampin (POH 7135)
    False-Positive Cultures for *Mycobacterium tuberculosis* (POH 7137)

20. **"Tuberculosis"** DPH Disease Fact Sheet Series, POH 4432. (http://www.dhfs.state.wi.us/healthtips/BCD/Tuberculosis.htm).

21. Wisconsin Department of Health and Family Services. **Wisconsin Administrative Rule, Control of Communicable Diseases,** Chapter 145.

22. Wisconsin Division of Public Health. **Infection Control Plan for Local Health Departments** (developed as a template for local health departments). 1998.

23. **Wisconsin Statues and Administrative Code Relating to the Practice of Nursing**, ss. 441 Wis. Stats., & Chapter N6 - Standards of Practice for Registered Nurses and Licensed Practical Nurses.

24. **Wisconsin Statutes, Communicable Diseases**; ss. 252.07 – 252.10; 1999.

25. **Wisconsin TB Program Strategic Plan for Elimination of TB in Wisconsin,** 2001.

26. **World Wide Web addresses**, National Model TB Centers & CDC:

    Harlem Model Center – www.harlemtbcenter.org
    New Jersey Model Center – www.umdnj.edu/ntbc
    San Francisco Model Center – www.nationaltbcenter.edu
    Centers for Disease Control and Prevention, CDC, Atlanta – www.cdc.gov

GUIDELINE for ESTABLISHING EFFECTIVE PRACTICE	Reviewed/Revised:
Ensuring Treatment Adherence & Completion & Providing DOT for Persons with Suspect or Active Tuberculosis Disease or Latent Tuberculosis Infection (LTBI)	Signatures & Dates: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
_____ Health Department Original Effective Date _____ Approved by _____	

GUIDELINE for PROCEDURE DEVELOPMENT

I. Terms and Definitions:

Adherence – Consistently maintaining a prescribed medication regimen as a result of a cooperative partnership in which the client participates fully and is supported by the provider, the two parties having shared responsibilities for treatment outcomes.

Culture Confirmed Tuberculosis – Tuberculosis disease that has been confirmed by culture-positive identification on a clinical specimen.

Directly Observed Therapy (DOT) – The ingestion of prescribed anti-tuberculosis medication that is observed by a health care worker or other responsible person acting under the authority of the local health department.

Drug Resistant TB – TB from a strain of *M. tuberculosis* that has the ability to grow and multiply in the presence of a drug that is usually effective against TB. Types of drug resistance include:

- **Acquired resistance –** A phenomenon in which exposure to a single drug, due to irregular drug supply, poor drug quality, inappropriate prescription and/or poor adherence to treatment suppresses the growth of bacilli susceptible to that drug but permits the multiplication of drug-resistant organisms.

- **Multi-drug resistance** – A condition in which the organisms in the body are resistant to at least isoniazid and rifampin.

- **Primary resistance** – Subsequent transmission of bacilli that are drug resistant to other persons that may lead to disease which is drug resistant from the outset, also known as transmitted resistance.

- **Transmitted resistance** – TB drug resistance that occurs when a strain of TB already resistant to one or more anti-TB drugs is transmitted to a new case and results in resistance to the same number and types of drugs as in the source case; also known as primary resistance.

Enablers – Things that help a person overcome other pressing needs in their lives that compete with treatment adherence or DOT, thus promoting and supporting completion of treatment.

Extrapulmonary tuberculosis – Tuberculosis in any part of the body other than the lungs.

High prevalence groups – Groups of people who are more likely to be exposed to and infected with TB, including close contacts of people with infectious TB, people born in areas of the world where tuberculosis is common, low-income groups with poor access to health care, elderly people, people who live or work in certain facilities, people who inject drugs and people in other locally identified groups.

High-risk populations – Certain demographic groups who are at a greater risk than the general U.S. public to contract a particular disease. In the case of TB, these groups include individuals who are economically disadvantaged; co-infected with HIV; foreign born; members of a racial or ethnic minority group; substance abusers; homeless persons, migrant workers; incarcerated; very young or advanced in age and those with medical risk factors for tuberculosis.

High-risk tuberculosis – An infection with tuberculosis that is highly likely to progress to active disease and may easily become infectious if it remains untreated.

Immunocompetent – Capable of producing normal or adequate immune responses.

Immunosuppression – The suppression of natural human responses to infection as caused by disease, malnutrition, or medical treatment involving drugs or irradiation.

Incentives – Rewards that are given to clients either to encourage them to take their medications or to adhere to regular clinic or field visits for DOT.

Infection – The condition in which organisms capable of causing disease enter the body and elicit a response from the host's immune system. TB infection may or may not lead to active TB disease, however persons with infection remain at life-long risk of developing active disease if their infection goes untreated. Also known as latent tuberculosis infection (LTBI).

Infectious tuberculosis – Tuberculosis disease of the respiratory tract, capable of producing infection or disease in others as demonstrated by the presence of acid-fast bacilli in the sputum or bronchial secretions or by chest radiograph and clinical findings.

Intermittent therapy – Medications administered two or three times per week, rather than daily. All intermittent therapy must be directly observed by a health care worker or other responsible person acting under supervision.

Interpretation – the oral restating in one language of what has been said in another language. Interpreted information should accurately convey the tone, level and meaning of the information given in the original language. (National Association of Judiciary Interpreters and Translators)

Laryngeal tuberculosis – Tuberculosis of the larynx; often considered more infectious than pulmonary TB; organisms are generally exhaled by the person with the disease.

Latent TB infection (LTBI) – Infection with *M. tuberculosis*, usually detected by a positive PPD skin test result, in a person who has no symptoms of active TB and no radiographic evidence of active TB and is not infectious. Tubercle bacilli are present in the body but the disease is not clinically active; same as TB infection.

Medicaid Tuberculosis-Related Benefit (MA TR Benefit) – A Medicaid benefit that covers TB clinical services for individuals meeting the financial eligibility requirements who are infected with tuberculosis or those who have active disease.

Relapse – Active TB that develops within the first two years after successful completion of therapy. In such cases of relapse, the organism often has a susceptibility pattern that is similar to that of the initial infection. The possibility of a new infection with *M. tuberculosis* should also be considered.

Suspect tuberculosis – An illness marked by symptoms such as prolonged cough, prolonged fever, hemoptysis; compatible radiographic or medical imaging findings; or laboratory tests that may be indicative of tuberculosis.

Symptomatic – Having symptoms that *may* indicate the presence of TB *or* another disease, such as cough, fever, night sweats, weight loss, hemoptysis, etc.

TB Case – A particular episode of clinically active TB. This is only used to refer to the disease itself, not the client with the disease. By law, cases of TB must be reported to the local health department as well as suspect tuberculosis as defined above.

Translation – the written conversion of written materials from one language to another.

Treatment failures – TB disease in clients whose disease does not respond to chemotherapy or in clients whose disease worsens after having improved initially. For a pulmonary tuberculosis case this is evidenced by a positive acid-fast sputum culture after 5 months of treatment. This can be the result of an inappropriate dosage or inadequate number of drugs, client nonadherence, malabsorption, or organism resistance.

II. Purpose:

This procedure will enable the Health Department staff to carry out the activities required for tuberculosis treatment adherence, completion of therapy and Directly Observed Therapy (DOT) using the priorities for services established by health department policy. DOT is utilized to ensure that the individual with suspect or confirmed tuberculosis completes medical treatment to prevent relapse, continued transmission and development of drug resistance. For those persons who are infected with tuberculosis, DOT is implemented to prevent progression to active disease and to progress toward the elimination of TB. These procedures will be implemented according to current CDC protocols and standards of practice for the protection of the health of the public and as specified in Wisconsin statutes and rules.

III. Persons Affected/Responsible:

This procedure will be carried out by _____ under the direction
(List staff positions affected)
of the health officer of the _____ Health Department.
City/County

"Noncompliance is now being called the most significant problem that tuberculosis program staff must face…"

Enablers and Incentives, Division of Tuberculosis Control, South Carolina Department of Health

IV. Suggested Procedure Language:

Recommendation: All care providers should read at least these resources prior to implementing this procedure:

- *The booklet entitled* "Improving Client Adherence to Tuberculosis Treatment", CDC, 1994
- *Chapter VII – Client Compliance (Adherence) – from the manual,* Tuberculosis Nursing: A Comprehensive Guide to Client Care. NTCA, 1997
- *The booklet entitled* "Enablers and Incentives", Division of Tuberculosis Control, South Carolina Department of Health

A. Establish agency plan that addresses the risks of treatment non-adherence, issues related to lack of treatment completion, full utilization of community resources and priority setting to protect the health of the public and meet standards of practice for tuberculosis care.

1. Place those with suspect or confirmed active disease as the first priority for health department assessment and intervention, including DOT, followed by those who are close or high-risk contacts to active disease and then others with LTBI.

2. Determine what resources are available in your community to streamline DOT when needed, such as jail nurses, parish nurses, school nurses, home health agency personnel, community support program staff, community leaders, other responsible persons, etc.

3. Evaluate and implement the Incentive Program for Tuberculosis Control administered by the American Lung Association of Wisconsin if indicated.

B. Assess client needs and environmental factors to guide development of individualized care and management, including DOT when indicated.

1. **Evaluate all persons who are referred for tuberculosis care, face to face, to determine the need for DOT both initially and on an ongoing basis.**

2. Validate information from referral and other sources. Collect and evaluate relevant new information.

3. Consult health officer or supervisor according to health department policy/procedure/practice regarding assessment findings and decision-making regarding DOT and document.

4. Assess for the potential negative effect, for disease transmission/progression if treatment is incomplete, as well as for the risk of non-adherence by the client. (*For example, is there a vulnerable population in the person's environment, such as young children or those who are HIV +, that make it imperative to halt potential transmission?*)

5. Assess and prioritize candidates for DOT based upon at least the factors listed below and on the comprehensive assessment findings. (*Make **no** assumptions; the higher the risk of non-adherence or potential disease transmission/progression, the more imperative it is to implement DOT to protect the health of the public. See sample assessment form in appendix as a decision-making aid, however no procedure detail or assessment form replaces the judgement of the public health nurses and the health officer*.)

   a) Consider DOT imperative with the presence of any of these factors –

      1. Prescription is for intermittent therapy
      2. Suspicion or confirmation of drug resistance to one or more TB drugs
      3. Infectiousness/potential for transmission (i.e. smear +, symptomatic, vulnerable contacts)
      4. HIV Positive
      5. Recurrent TB disease
      6. History of non-adherence to prescribed TB medications
      7. Lack of sputum clearing or lack of clinical improvement despite treatment.
      8. Homeless, or staying in a shelter or in a tenuous living situation; flight risk
      9. Using IV drugs, using excess alcohol, other substance abuse
      10. Young age of suspect/case with active disease (i.e., under age 18)
      11. Close or high-risk contact (young child or HIV+) on window prophylaxis
      12. History/presence of mental, physical, developmental, cognitive illness or disability, no caregiver
      13. Too ill, elderly, frail, impaired or forgetful to self-manage, no caregiver

   b) Give strong consideration to DOT with the presence of any of these factors which indicate a high risk for negative outcome or client non-adherence if DOT is not implemented –

      1. Extrapulmonary TB with any medical or nonadherence risk factors
      2. Children on LTBI therapy whose parents have any medical or nonadherence risk factors

3. Adherence questionable, vulnerable persons present (HIV +, young children)
4. History or presence of alcohol or other substance use
5. History or current adverse reactions or side effects attributed to TB drugs
6. History of poor adherence during any medical management
7. Denial/refusal to accept TB diagnosis (may believe BCG provided protection, etc.)

c) Consider that without DOT, the presence of any of these factors indicates a risk is evident for disease progression if treatment is incomplete –

1. History of incarceration; life rebuilding is taking priority (work, housing, etc.)
2. Lack of insight/understanding of the potential negative medical effects of non-adherence
3. Cultural risk factors – Language/communication/family issues, distrust of the health care system
4. Avoidance of government/authorities/institutions for fear of revealing immigration status
5. Past/current negative experience with social service, health care or third party payors
6. Subject to poverty, unemployment, underemployment, uninsured/underinsured
7. Preoccupation with other economic, family, social or substance abuse issues
8. Any other individual reasons that point to potential difficulty taking medications, such as difficulty swallowing pills, etc.

6. Document the assessment findings that are present or absent, the comprehensive assessment, and any consultation or decision-making with supervisory staff or the health officer for DOT prioritization.

7. Assess for and respect cultural, individual and family differences that will contribute to development of strong, trusting relationships with the person and the family thus increasing the likelihood of adherence to therapy.

8. Determine the need for interpreters and/or translators and provide or arrange for services as needed taking into account at least the following considerations: (*See appendix for additional information on cultural concepts.*)

a) Avoid use of family members, especially children.
b) Use trained medical interpreters whenever possible to avoid lack of understanding of medical/health care terminology.
c) Keep in mind that there may be no equivalent word in the client's language and the interpreter may interject their own interpretations or misunderstandings may occur.
d) Recognize that client and family may be reluctant to reveal information through a third party due to fear of lack of confidentiality, especially about sensitive information.
e) Assure confidentiality of information when using interpreters/translators and adhere to agency confidentiality policies and procedures. Reassure clients and families that measures are taken to ensure confidentiality.
f) Talk with the interpreter before the interviews and ensure that the interpreter uses the client's own words for translations; keep words simple and concrete.

g) Address client directly (not interpreter) and maintain eye contact unless this is culturally offensive to the client or they have not adapted to this practice in American culture.
h) Watch clients and family members for cues and convey through your body language, expression and tone that you care, despite language barriers.
i) Use correct pronunciation of client's names and some key phrases related to TB in the client's language if possible.
j) Familiarize yourself with the history and culture of the racial or ethnic populations served.

Build knowledge of various cultures into your practice ***while continuing to recognize that each person is unique***.

9. Assess client and family's knowledge about their condition and determine and implement appropriate education and the strategies needed to ensure completion of treatment.

10. Correct myths and misunderstandings early in treatment and provide clients and families with accurate facts about tuberculosis and what is needed for cure.

C. Individualizing strategies to increase adherence and implementing DOT

1. Develop an individualized approach to each client's care, including DOT when indicated. (*See document in appendix entitled "Elements of a Treatment Plan for TB Clients" for a framework.)*

2. Develop individualized treatment adherence strategies that encourage success for *all* clients, especially if DOT is not implemented, by doing at least the following:

   a) Foster client and family participation at all levels including selecting the approaches for care, such as the time and place for visits. Also consider partial DOT if appropriate.

   b) Utilize the person's interests and motivating factors, especially in selecting incentives and enablers for adherence, regardless of DOT status. (*Begin with small incentives to allow trust to build and to avoid overwhelming the person.*)

   c) Utilize the client's personal strengths, support systems and local resources to overcome barriers to adherence, capitalizing on their need to protect those who are important to them.

   d) Remain open to the potential need to change and vary approaches, incentives and enablers as the treatment plan progresses and relationship with client evolves.

3. Revise approaches when indicated based upon ongoing assessment and evaluation, share changes with team members and document accordingly.

   a) Follow health department policies, procedures and standards of practice for persons employed by the health department or other responsible persons used to assist with DOT. (*See appendix for supportive documents: DOT by Responsible Persons, Skill & Training Checklist, Sample Tool for Volunteer Recording and Medication Monitoring Form.*)

4. Document DOT method, if DOT is utilized, according to health department procedure. This can be done on the Client Drug Receipt/Delivery Form. (*See guideline for Accessing Services & Resources for sample.*)

5. Document number of doses taken and/or number of doses missed on Client Drug Receipt/Delivery Form or as otherwise specified by health department policy, procedure or practice.

6. Document comprehensive assessment of client's medication adherence, any medical or adherence issues noted and what actions are taken in narrative notes as appropriate.

7. Protect the health of the public by issuing a Health Officer order for DOT if deemed necessary or by obtaining a **court order** for DOT if client does not adhere to prescribed medication and presents a risk to the health of the public. (*See health department policy and sample Court Order in Appendix for all required components and documentation required by the court to take action according to statute. See sample Health Officer order in Isolation Guideline*.)

D. Using Incentives and Enablers

Introduction

The Tuberculosis Control Incentive Program administered by the American Lung Association of Wisconsin is designed to assist you with the treatment of tuberculosis clients by providing funding to purchase incentives and enablers that will encourage clients to complete therapy. The statewide incentive program is federally funded by CDC through the State of Wisconsin Division of Public Health's Tuberculosis Program. Funding for the City of Milwaukee's TB incentive program is primarily provided by a private donation from Fortis Insurance Company.

The program is to be used primarily for clients who have active TB disease but can also be used for clients on treatment for Latent Tuberculosis Infection (LTBI) to encourage and reward them along the course of their treatment. Being on medications for weeks, months, or in some cases, years, is not easy. Everyone receiving TB treatment needs the support and encouragement of their health care workers. Experienced tuberculosis control programs have proven that the minimal costs for providing incentives and enablers is well worth the effort. *Enablers and Incentives* by the South Carolina Department of Health and Environmental Control and the American Lung Association of South Carolina, and *Tuberculosis Nursing: A Comprehensive Guide to Client Care* by the National Tuberculosis Controllers Association both provide excellent perspective on the delivery of meaningful care that encourages persons battling tuberculosis to sustain their efforts.

Procedures

1. Enroll in the American Lung Association of Wisconsin's Tuberculosis Control Incentive Program by filling out the Tuberculosis Control Incentive Program **Enrollment Form** (see Appendix) or by sending a letter or fax to the American Lung Association of Wisconsin expressing your health department's interest in participation in the program. The letter should preferably be written on health department letterhead and should be

signed by the individual who will thereafter serve as the contact to the program. Send or fax the enrollment form or letter to:

The American Lung Association of Wisconsin
Tuberculosis Control Incentive Program Coordinator
150 S. Sunny Slope Road, Suite 105
Brookfield, WI 53005-4857
1-800 LUNG USA
FAX: (262) 782-7834.

After the American Lung Association of Wisconsin receives your enrollment form or letter, the program will send out:

- a welcome letter
- educational materials
  -*Enablers and Incentives* by the South Carolina Department of Health and Environmental Control and the American Lung Association of South Carolina
  -an excerpt from *Tuberculosis Nursing: A Comprehensive Guide to Client Care* by the National Tuberculosis Controllers Association
- a purchase log, a disbursement record, and a reimbursement request form
- a start-up check of $100 to be deposited in the health department's account for initial tuberculosis incentive/enabler purchases

2. Make copies of the purchase log, disbursement record, and reimbursement request forms and retain the "originals" for your future use.

3. Purchase incentive items for your tuberculosis clients using the money provided. Types of items that can be purchased may be as far reaching as your imagination with the exception of cigarettes, alcohol, and health services such as x-rays and any over-the-counter medications. Usual incentives cost under $10. Remember that an incentive need not be expensive to be meaningful to a client. Typical items include pill minders, food, beverages, school supplies, plants, bus tickets, gas vouchers, flowers, birthday cards, even fishing lures. It is important to base incentive purchases on your knowledge of the client and to make them as personally meaningful to the client as possible. Listen to your clients, and as you build rapport with them, learn their interests. This will enable you to choose meaningful incentives for them. Begin right away with small items while the nurse-client bond is forming.

   Sometimes, it may be appropriate to spend a bit more on a client if they have a particular need (they are contagious and need help paying rent so as not to become homeless), or have reached an important milestone in treatment (they have completed one year of therapy for multidrug-resistant TB). If such special cases arise, clear your purchase first. Call the American Lung Association's TB Control Incentive Program Coordinator at (262) 782-7833 to ensure the availability of funding to fulfill your request.

4. Fill out the **purchase log** (sample in Appendix) for each set of items you purchase and attach your receipts to the log for the items purchased. Make a separate entry in the log for each receipt you submit.

5. Fill out the **disbursement record** (sample in Appendix) each time you provide an incentive to a client. First, record the date the incentive was provided to the client. Then record the confidential client identification information (client's name, initials or identification number assigned by the Wisconsin TB Program) and the client's date of birth for client tracking purposes (clients need not sign the record themselves). Make one check in either the "Suspect/Active TB Case" or the "Latent TB Infection" column to indicate what type of tuberculosis the client has. Indicate what type of incentive was used, and finally, its value or approximate value.

6. Fill out the **reimbursement request** (sample in Appendix) at the time you decide to request reimbursement from the American Lung Association of Wisconsin. Indicate to whom/what agency the check should be made payable, to whom the check should be mailed to the attention of, your agency name, and the correct address the check should be mailed to. Indicate the total amount you are requesting to be reimbursed (which should match the total amount on the purchase log and be equal to the attached receipts). Sign and date the request.

7. You may submit the purchase log with attached receipts, the disbursement record, and the reimbursement request to the American Lung Association of Wisconsin at any time you would like to be reimbursed. You need not wait until you have spent the entire $100, as is it is intended to form a base for your incentive account from which you may draw. When the American Lung Association receives the forms, they will process them and send you a check for the amount of money you have used within three weeks.

8. Submit all forms and receipts before December 15th of each calendar year so that the American Lung Association of Wisconsin can track the clients served within that year. Activity for December 15th to 31st may be carried over to the following year.

9. You may discontinue participation in the Tuberculosis Control Incentive Program at any time. Resignation from the program requires that the $100 used as a base for the incentive account be returned to the American Lung Association of Wisconsin accompanied by a letter clearly stating your agency's desire to resign from participation in the program. Lack of activity in the Tuberculosis Control Incentive Program does not mandate resignation from the program, as it is understood that significant time periods may be experienced between tuberculosis clients.

VII. References Used for State Guideline Development

[*The following references were used to develop the model state guideline. Any additional references used by the local health department should also be listed in the final policy and procedure document.*]

1. American Academy of Pediatrics. **Red Book 2000, Report of the Committee on Infectious Disease**, 25th Edition, 2000.

2. American Thoracic Society and Centers for Disease Control and Prevention. **Diagnostic Standards and Classification of Tuberculosis in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, April, 2000, 161:1376-1395.

3. American Thoracic Society. **Treatment of tuberculosis and tuberculosis infection in adults and children.** American Journal of Respiratory and Critical Care Medicine, 1994; 149: 1359-74.

4. Bartlett, E.E., Behavioral Diagnosis: A Practical Approach to Client Education, **Client Counseling and Health Education.** 1982; 4(1):29-35.

5. California Department of Health Services and California Tuberculosis Controllers Association Joint Guidelines. **Directly Observed Therapy Program Protocols in California**. 1997.

6. CDC Division of AIDS, STD and TB Laboratory Research, Tuberculosis/Mycobacteriology Branch, www.cdc.gov/ncidod/dastlr/TB/TBpublications.htm.

7. Centers for Disease Control and Prevention. **Core Curriculum on Tuberculosis: What the Clinician Should Know**. Fourth Edition, 2000.

8. Centers for Disease Control and Prevention. **Forging Partnerships to Eliminate Tuberculosis**. 1995.

9. Centers for Disease Control and Prevention. **Improving Client Adherence to Tuberculosis Treatment**. 1994.

10. Centers for Disease Control and Prevention. Morbidity & Mortality Weekly Report, Volume 44/No. RR-11. **Elements of a Treatment Plan for TB Clients**.

11. Centers for Disease Control and Prevention. **Self-Study Modules on Tuberculosis**. Modules 1-5, 1995. Modules 6-9, 2000.

12. Centers for Disease Control and Prevention. **Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**. MMWR April, 2000;49 (No. RR-6).

13. Division of Public Health, Bureau of Communicable Diseases. **EPINET, Wisconsin Disease Surveillance Manual** [*Updated periodically on the Health Alert Network (HAN).*]

14. Division of Tuberculosis Control, South Carolina Department of Health and Environmental Control, **Enablers and Incentives**, 1989.

15. National Tuberculosis Controllers Association. **Tuberculosis Nursing: A Comprehensive Guide to Client Care**, 1997.

16. New Jersey Medical School National Tuberculosis Center. **Tuberculosis Glossary**, 1995 & **Tuberculosis School Nurse Handbook**, 1998.

17. North Carolina Division of Epidemiology, Department of Health and Human Services. **North Carolina Tuberculosis Policy Manual**. 1997.

18. Pickering, L.K., ed. **Tuberculosis**. In: 2000 Red Book: Report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2000, 593-613.

19. **TB Fact Sheet Series** found at http://www.dhfs.state.wi.us/dph_bcd/TB/Resources/TB_resources2.htm.

    Sputum Conversion during TB Treatment, (POH 7131)
    Rifater and Rifamate in the Treatment of TB (POH 7133)
    Tuberculin Skin Testing for Suspected TB (POH 7134)
    The Importance of Rifampin (POH 7135)
    False-Positive Cultures for *Mycobacterium tuberculosis* (POH 7137)

20. **"Tuberculosis"** DPH Disease Fact Sheet Series, POH 4432. (http://www.dhfs.state.wi.us/healthtips/BCD/Tuberculosis.htm).

21. Wisconsin Department of Health and Family Services. **Wisconsin Administrative Rule, Control of Communicable Diseases,** Chapter 145.

22. Wisconsin Division of Public Health. **Infection Control Plan for Local Health Departments** (developed as a template for local health departments). 1998.

23. **Wisconsin Statutes and Administrative Code Relating to the Practice of Nursing**, ss. 441 Wis. Stats., & Chapter N6 - Standards of Practice for Registered Nurses and Licensed Practical Nurses.

24. **Wisconsin Statutes, Communicable Diseases**; ss. 252.07 – 252.10; 1999.

25. **Wisconsin TB Program Strategic Plan for Elimination of TB in Wisconsin,** 2001.

26. **World Wide Web addresses**, National Model TB Centers & CDC:

    Harlem Model Center – www.harlemtbcenter.org
    New Jersey Model Center – www.umdnj.edu/ntbc
    San Francisco Model Center – www.nationaltbcenter.edu
    Centers for Disease Control and Prevention, CDC, Atlanta – www.cdc.gov

APPENDIX CONTENTS

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

ASSESSMENT for DISEASE RISK/NONADHERENCE RISK FACTORS

Name _____ DOB _____

Assess for the potential negative effect on the medical/disease condition if prescribed medications are not taken for *any reason* as well as for the risk of non-adherence by the client. Assess for the need for DOT initially and on an ongoing basis using at least these factors **plus** your comprehensive assessment. Base decisions regarding interventions, including the need for DOT, on the need to protect the health of the public. Seek supervisory input and prioritize according to health department policies. **The higher the risk of non-adherence or potential disease progression, the more imperative it is to implement DOT. The greater the number of factors present, the greater the need for DOT.**

Assessment factors for Disease Risk & Nonadherence Risk	No	Yes	If Yes, DOT Imperative
Prescription is for intermittent therapy			
Suspicion or confirmation of drug resistance to one or more TB drugs			
Infectiousness/potential for transmission (i.e. smear +, symptomatic & vulnerable contacts)			
HIV Positive			
Recurrent TB disease			
History of non-adherence to prescribed TB medications			
Lack of sputum clearing or lack of clinical improvement despite treatment			
Homeless, or staying in a shelter or in a tenuous living situation, flight risk			
Using IV drugs, using excess alcohol, other substance abuse			
Young age of suspect/case with active disease (i.e., under age 18)			
Close or high-risk contact (young child or HIV+) on window prophylaxis			
History/presence of mental, physical, developmental, cognitive illness or disability, no caregiver			
Too ill, elderly, frail, impaired or forgetful to self-manage, no caregiver			
Assessment factors for Disease Risk & Nonadherence Risk	**No**	**Yes**	**If Yes, High Risk Indicator**
Extrapulmonary TB with any medical or nonadherence risk factors			
Children on LTBI therapy whose parents have any medical or nonadherence risk factors			
Adherence questionable, vulnerable persons present (HIV +, young children)			
History or presence of alcohol or other substance use			
History or current adverse reactions or side effects attributed to TB drugs			
History of poor adherence during any medical management			
Denial or refusing of TB diagnosis (may believe BCG provided protection, etc.)			
Assessment factors for Nonadherence Risk	**No**	**Yes**	**If Yes, Risk Evident**
History of incarceration; life rebuilding is taking priority (work, housing, etc.)			
Lack of insight/understanding of the potential negative medical effects of nonadherence			
Cultural risk factors – Language/communication/family issues, distrust of the health care system			
Past/current negative experience with social service, health care or third party payors			
Avoidance of authorities/institutions for fear of revealing immigration status			
Subject to poverty, unemployment, underemployment, uninsured/underinsured			
Preoccupation with other economic, family, social or substance abuse issues			
Other reasons that indicate potential difficulty taking medications			

See narrative notes for comprehensive assessment, supervisory consultation, rationale for decision-making or other adherence strategies implemented.

ÿ **DOT will be provided** ÿ **DOT will not be provided**

_____ _____
PHN Signature *Date*

"What we do is whatever it takes." *Arkansas Public Health Nurse*

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

RECOMMENDED TUBERCULOSIS NURSING ACTIVITIES for ENSURING ADHERENCE & COMPLETION and PROVIDING DOT		
Procedure	**TB Nursing Action**	**Recommended Time Frames**
Assess client for DOT Services	Comprehensive assessment [See form option] Evaluate findings Determine DOT according to protocol and/or implement supports for medication adherence	Within 3 days
Determine who will do DOT	Assign responsibility for DOT and provide instructions/education commensurate with skills, duties and client condition: Assure person is trained in infection control procedures & any personal protective measures or equipment if needed Review medical orders with person assigned, if appropriate Describe dosage, route, & frequency of medication if appropriate Provide instructions for and a method of recording each dose if they will be recording Instruct in what to report Provide numbers and contact persons to be reached if problems develop	Within 3 working days
Determine frequency of DOT	Obtain physician signature for any adjustment of drug dosage Contact DOT worker regarding any changes in the medical regimen Assure changes in medical regimen are documented on the DOT documentation form	Medical regimens are usually daily for 2 weeks, then intermittent therapy
Determine the location of DOT	Decide mutually with the client where the DOT will be given Assure flexibility about the time Preserve confidentiality Consider and implement appropriate enablers Consider and implement appropriate incentives	During initial visit and ongoing
Obtain a signed client contract for DOT	Obtain client signature on client DOT contract Obtain witness signature on client DOT contract	As soon as possible following initial contact
Document each dose of DOT	Assure documentation of each drug dose on documentation record Complete a review at least monthly of documentation record to ascertain DOT is being maintained	Ongoing
Develop a case management plan	Follow elements of a treatment plan for TB clients Assure monthly review according to protocol is part of case management plan	Ongoing

SAMPLE VOLUNTARY CONTRACT FOR DIRECTLY OBSERVED THERAPY (DOT)

To: _____ Date of Birth: _____
Client Name

Dr. _____, a physician licensed to practice medicine in the State of Wisconsin, has determined that you have tuberculosis. Tuberculosis treatment is difficult because it requires taking several medications for at least six to nine months. Most people find it difficult to remember to take their medications, or they stop taking them when they start to feel better. When this happens, a person with tuberculosis can get sick again, and the tuberculosis germ could even become resistant to the medications, making it harder than ever for the person to get well.

To help you remember to take all of your medications, (_____)
(Names of involved persons)
will meet with you and stay with you to observe you swallow the medications. This is called Directly Observed Therapy or DOT for short. Directly Observed Therapy is convenient and easy to arrange and it will be fit into your daily routine. You, your physician, your public health nurse and a trained Directly Observed Therapy worker become a team. All of you work together to make sure you are getting better. People who are helping you remember to take your medication may also be able to help you if there are other problems that interfere with your treatment. Let them or your case manager know if you have any problems.

If you stop taking your medications before the physician tells you to stop, or you only take it once in a while, your tuberculosis can come back worse than before. Then it is harder to treat and takes longer. Please sign the following voluntary contract so that we know you understand the importance of treatment for your tuberculosis.

I, _____, agree to take medications as ordered by my physician.
Client Name

I understand that the number of medications I take and the number of days that I have to take them may change according to what is best to treat my tuberculosis and will be done according to my physician's orders. I understand that I will be kept informed of any changes, will be given opportunities to understand these changes and that my questions will be answered.

I agree to meet with the person(s) helping me remember to take my medications at the agreed upon locations(s) every day, until treatment is changed to only two or three times per week.

After the treatment is changed to two or three times per week, I will meet with the persons(s) on the days I need to take medications at the location(s) and times to which we agree.

I agree to let my case manager know if there are any problems with taking my medications and I will immediately make alternative plans if a day, time or location presents a problem for me so that my treatment is not interrupted.

_____ _____
Client Signature Date

_____ _____
Witness Signature Date

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

ELEMENTS OF A TREATMENT PLAN FOR TB CLIENTS from
Vol.44/No.RR-11, **MMWR**

I. Assignment of responsibility
- A. Case manager (e.g., person assigned primary responsibility)
- B. Clinical supervisor (e.g., nurse, physician, physician assistant)
- C. Other caregivers (e.g., outreach worker, nurse, physician, physician assistant)
- D. Person responsible for completing contact investigation.

II. Medical evaluation
- A. Tests for initial evaluation (e.g., tuberculin skin test, chest radiograph, smear, culture, susceptibility tests, HIV test) results of each test and date completed
- B. Important medical history (e.g., previous treatment, other risk factors for drug resistance, known drug intolerance, and other medical problems)
- C. Potential adverse reactions
  1. Appropriate baseline laboratory tests to monitor toxicity (e.g., liver enzymes, visual acuity, color vision, complete blood count, audiogram, BUN, and creatinine), including results of each test and date completed
  2. Potential drug interactions
- D. Obstacles to adherence

III. TB treatment
- A. Medications, including dosage, frequency, route, date started, and date to be completed for each medication
- B. Administration
  1. Method (directly observed or self-administered)
  2. Site(s) for directly observed therapy

IV. Monitoring
- A. Tests for response to therapy (e.g., chest radiograph, smear, and culture), including planned frequency of tests and results
- B. Tests for toxicity, including planned frequency of tests and results

V. Adherence plan
- A. Proposed interventions for obstacles to adherence
- B. Plan for monitoring adherence
- C. Incentives and enablers

VII. TB education
- A. Person assigned for culturally appropriate education
- B. Steps of education process and date to be completed

VIII. Social services
- A. Needs identified
- B. Referrals, including date initiated and results

IX. Follow-up plan
- A. Parts of treatment plan to be carried out at TB Clinic
- B. Parts of treatment to be carried out at other sites and person(s) conducting activities

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

STATE OF WISCONSIN, CIRCUIT COURT, _____ COUNTY		
State of Wisconsin, Plaintiff, -vs- _____, Defendant Name _____ Date of Birth	**Order of Commitment for Directly Observed Therapy for Treatment of Tuberculosis** Case No.	**For Official Use**

THE COURT FINDS:

1. The defendant:
   - ❑ has been informed of the need, both verbally and in writing by the local health officer, to voluntarily take medication for tuberculosis to protect the health of the public, **and**
   - ❑ did not voluntarily comply with the order made by the local health officer to take tuberculosis medications.

Violation(s)	**Wis. Statute(s) Violated**	**Date(s) of violation(s)**

2. The defendant is competent to proceed at this time.

3. A written statement from a physician has been presented that verifies that the defendant has:
   - ❑ infectious tuberculosis; **or**
   - ❑ noninfectious tuberculosis but is at high risk of developing infectious tuberculosis; **or**
   - ❑ suspect tuberculosis.

4. Evidence has been presented to the court that the defendant has refused to follow a prescribed treatment regimen.

5. Evidence that all other reasonable means of achieving voluntary compliance with tuberculosis treatment have been exhausted and no less restrictive alternative exists.

6. A written statement has been presented to the court by the Local Health Officer or the Wisconsin Department of Health and Family Services (DHFS) that the defendant poses an imminent and substantial threat to himself or herself and the health of the public.

IT IS ORDERED:

1. These proceedings are suspended.
2. The defendant is committed to **DIRECTLY OBSERVED THERAPY WITH TUBERCULOSIS MEDICATIONS** that are provided:
   - through the _____Health Department,
   - as prescribed by a licensed physician, and
   - as dispensed by a registered pharmacist, and
   - as authorized for payment by the Wisconsin Department of Health and Family Services (DHFS).
3. The health department, physician, pharmacist and DHFS shall observe appropriate medical and public health standards in the treatment of the defendant.
4. Other: _____
5. In the event the defendant fails to comply with this order, the defendant may be subject to isolation or confinement pursuant to ss. 252.07(8) and (9), Wis. Stats., or to other and additional sanctions as this Court may determine.

	BY THE COURT:
Distribution: Court – Original Health Officer, local health department District Attorney Defendant/Counsel Physician Dept. Health & Family Services, Div. Public Health	_____ Circuit Court Judge _____ Name Printed or Typed _____ Date

DIRECTLY OBSERVED THERAPY (DOT) BY RESPONSIBLE PERSONS

DOT definition – the ingestion of prescribed anti-tuberculosis medication that is observed by a health care worker or other responsible person acting under the authority of the local health department.

DOT done by unlicensed assistive personnel is addressed in the document entitled "Directly Observed Therapy by Unlicensed Assistive Personnel, Model Policy and Procedure for Public Health Tuberculosis Programs" issued in 1995. This document should continue to be used as a model for updating policies and procedures in the local health department when persons are employed by the health department for the role of DOT worker.

The public health department has final responsibility for adherence to antituberculosis medication, it is not the responsibility of the client. The health department must do whatever it takes to ensure medication adherence within the priorities established by health department policies. If the services or supports the health department provides or arranges for meet the definition of a delegated nursing act, public health nurses will follow the nurse practice act.

DOT remains the standard of practice for treatment of persons with tuberculosis whether or not it is classified as a delegated nursing act. When responsible persons do DOT, helping tuberculosis clients adhere to their medication regimen by observing them ingest their medications on a regular basis, the individual needs of the client need to be met.

Here are some options for implementing DOT, including some rationale:

1. The nurse can administer the medication to the client from a prescriptive supply, kept in the home or the health department, and observe the client ingest the medication.

2. Unlicensed assistive personnel employed by the health department can observe the ingestion of the medication according to the policies and procedures established by the local health department that have been modeled after the 1995 document mentioned above.

3. Personnel of other employers (school nurses, prison or jail employees, home health staff, etc.) can assist with DOT under their own employer's policies and procedures with the public health nurse serving as case manager. This is a shared responsibility, arranged through another employer under policies, procedures or practices that have been reviewed and approved by the local health department. This may be arranged for under a verbal or written agreement.

4. Responsible persons who are willing and able to observe persons with tuberculosis ingest their medications on a regular basis have been used successfully to increase medication adherence and completion of treatment success rates in public health. The public health department needs to determine how to best achieve adherence to medications for their clients. Publications and resources in the reference list and those available from the reference websites provide additional information. Assistance from the regional public health nurse consultants and the TB program is available to help with this plan.

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

SKILL and TRAINING COMPONENTS for STAFF or RESPONSIBLE PERSONS DOING DOT

Assess learning styles and existing skills. Provide education & training in the areas needed to ensure competency that is consistent with all *applicable* skills and knowledge required by the duties the staff or responsible person performs. Skills or knowledge not required for the duties performed may be assessed as "not applicable".
Re-evaluation of competencies should be ongoing and at least annually and all applicable learning needs fulfilled.

Name of staff or responsible person _____

Training, Skills and Education	Date Completed	Initials of Evaluator
Knowledge of the Community		
Public Health, Medical and Laboratory services provided in the community		
Integration/collaboration with Health Care, Social Services & Community groups		
Geography of the region - specific community areas, travel, safety, etc.		
Population groups to be served		
Communication Skills/Accepting Delegation		
Willingness to accept delegation and/or instructions for client care/DOT		
Basic cultural competency for all cultures and ethnic groups served		
Special skills/training to serve persons who are homeless, substance abusers, or are disenfranchised		
Skills/training needed to accept and work effectively with all populations served		
Language Skills		
Speak the language of the population served or effectively work with interpreter services		
Use of correct name pronunciation & learning as much language as possible		
Specific field etiquette for the cultures of the persons served		
Confidentiality		
Health Department policy & procedure for medical record/information confidentiality/privacy [*Only those who need to know have a right to know*.]		
Personal dignity, privacy and building trust		
Respecting individual's boundaries while still protecting the health of the public		
Initial Training – CDC materials and modules may be used [www.cdc.gov/phtn/tbmodules]		
TB disease, infection, nature of TB diagnosis, transmission, prevention		
The medical order and rationale for prescribed medication(s)		
Review, describe actions, side effects & adverse reactions of prescribed medication(s)		
Review/describe: client identification, medication(s), dosage, route, frequency and adverse reaction		
Job duties, handling medication packets, observing self-administration, withholding medication(s)		
Observing, reporting & documenting client condition, side effects, adverse reactions		
Using meaningful incentives and enablers		
Working with the DOT team/field staff – documentation, urgent reports, case conferences, joint visits		
Infection control, bloodborne pathogens, standard & transmission-based precautions, fit testing and respiratory protection		
Personal protection & safety, personal safety in the community per OSHA & Department of Commerce requirements		
Handling Emergency Situations - CPR/Emergency Response/Fire Safety/Reporting		
Other:		

Initials ____ Signature _____ Initials ____ Signature _____
Initials ____ Signature _____ Initials ____ Signature _____
Initials ____ Signature _____ Initials ____ Signature _____

SAMPLE TOOL: VOLUNTEER'S RECORD OF D O T

Name _____ Date of Birth _____ Physician _____
Address _____ Phone _____

Optional TB Drug List:

Name of medication	Dose	Start date	Stop date

Client is on medication (s) (check one) ____ **Daily** ____ **2 X/wk** ____ **3 X/wk**

Please initial in appropriate day/month for each dose observed. Report to nurse as instructed.

Date	Time	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
16													
17													
18													
19													
20													
21													
22													
23													
24													
25													
26													
27													
28													
29													
30													
31													

Signature _____ Initials ___ Signature _____ Initials ___
Signature _____ Initials ___ Signature _____ Initials ___
Signature _____ Initials ___ Signature _____ Initials ___
Signature _____ Initials ___ Signature _____ Initials ___

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

LOCAL HEALTH DEPARTMENT

MONITORING TOOL FOR DOT

Client's Name: _____Case Code: _____
Birthdate: _____
Prescribing Physician: _____Diagnosis: _____
Client is on therapy (check one): _____ daily _____ 2x per week _____ 3x per week

PRESCRIBED MEDICATIONS FOR DOT Date MEDICATION LIST: Name, Dosage, Route, and Frequency												
		Time	Time	Time	Time	Time	Time	Time	Time	Time	Time	Time
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
Signature (initials)												

Note: Any changes in prescribed, discontinued, or held medications must be documented above.

Public Health Nurse Name _____**Signature/(Initials)**_____**(_____)**
Public Health Nurse Name _____**Signature/(Initials)**_____**(_____)**
Public Health Nurse Name _____**Signature/(Initials)**_____**(_____)**
Public Health Aide/Clinic Aide/Outreach Worker Name _____**Signature/(Initials)**_____**(_____)**
Public Health Aide/Clinic Aide/Outreach Worker Name _____**Signature/(Initials)**_____**(_____)**
Public Health Aide/Clinic Aide/Outreach Worker Name _____**Signature/(Initials)**_____**(_____)**

Revised 10/01 pdb

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

MEDICATION MONITORING FORM

Name	Birth Date	Physician
Address	Telephone	Telephone
TB Drugs: Name/Dose/Date Started/Date Stopped Other Drugs (Including Alcohol):		

Date												
Weight (lbs.)												
Pregnant Y/N												
Oral Contraceptives Y/N (RIF)												
Soft Contact Lens Y/N (RIF)												
Drug Side Effects: Y-Yes N-No N/A-Not Applicable P-See Progress Notes												
Unusual Tiredness, Weakness (EMB/INH/PZA/RIF)												
Clumsy/Unsteady (INH/SM)												
Numbness/Tingling/Burning Extremities (EMB/INH/SM/B6)												
Fever (PZA/RIF)												
“Flu” Like Symptoms (RIF)												
Chills/Joint Pain with Swelling (EMB/PZA/RIF)												
Deafness/Tinnitus (SM)												
Eye Pain/Blurred Vision (EMB/INH)												
Photosensitization (PZA)												
Yellow Eyes/Skin (INH/PZA/RIF)												
Rash/Hives/Pruritus (INH)												
Orange Body Secrections (RIF)												
Dark Urine (INH/PZA/RIF)												
Bloody/Cloudy Urine (RIF)												
Decreased Frequency/Amount of Urine (RIF/SM)												
Anorexia/N & V (INH/PZA/RIF)												
Right Upper Quadrant Pain (INH/PZA/RIF)												
TB Symptoms (cough, fever, hemoptysis, night sweats, weight loss, loss of appetitie) Y/N												

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

Name	Date of Birth											
Date												
Client Reports Number of Days Meds Missed this Month												
Med Count (if done) Compliant? Y/N (RN Assessment)												
Screens and Lab Tests: Enter the findings; a date; Y, N, N/A, P, as appropriate*												
Visual Acuity (EMB): Right												
Left												
Both												
Red/Green Color Normal Y/N (EMB)												
Hearing Test Y/N (SM)												
AST/ALT Done Y/N (INH) (SGOT/SGPT)												
Sputum Done Y/N												
Date Last MD Contact												
Date Next MD Appointment												
Continue Drugs Y/N **												
Next Follow-Up Visit												
RN Signature _____ _____												

* Enter **Y** if test done, **N** if not done, **NA** if Not Applicable and **P** to see Progress notes for detailed information.

** Confer with DPH Tuberculosis Program regarding drug continuation whenever there are questions/issues.

A few words about cultural competency:

When working with an individual from a culture different than yours keep in mind that basic client care skills are always helpful. Active listening, curiosity, maintaining an open mind and displaying a general positive regard for the client, their family and their well-being will always take you a long way in creating a constructive working relationship.

Prior to meeting with the client, learn what you can about the client's culture, the common health care beliefs of the culture and what circumstances have led them to your community. There are many excellent online web pages that can give you some basic understanding of the individual country and the culture (see the WI TB Program web page for a listing of Cultural and Linguistic Competency Resources from CDC). Volunteer Agencies (VOLAGS) that sponsor refugees coming to your area are also good resources for information on their clients' culture and the situation(s) from which they are emerging. Keep in mind that while you learn something about the culture through what you read or hear, what you experience with the client may be different. Many factors come into play such as their level of education, time in the United States, trauma they may have experienced and the current acculturation process they are going through. Knowledge about his or her culture and homeland is very helpful but also **view each person as unique**.

Keep in mind that cultural competence mandates that organizations, programs and individuals must have the ability to:

1. Value diversity and similarities among all peoples;
2. Understand and effectively respond to cultural differences;
3. Engage in cultural self-assessment at the individual and organizational levels;
4. Make adaptations to the delivery of services and enabling supports; and
5. Institutionalize cultural knowledge.

Translation

Do not use a family member as a translator, especially a child. Clients may be unwilling to disclose important information to a family member acting as a translator. Family members are not prepared in medical terms and they may interject their opinions without conveying the facts. It is critical that minor children (children in general but especially minor children) not be used because:

- it creates a break in family roles/structure,
- it may traumatize the child (knowing one's parent is ill increases fear and stress),
- they may lack the vocabulary and,
- the information needed is inappropriate to request via children.

Hiring bilingual staff can prevent using a family member as a translator for clients. For an initial visit (and until a local translator can be found for that language) a service like the AT&T Language Line can be very useful when a client who speaks a language that none of your staff know walks into your office.

APPENDIX - Ensuring Treatment Adherence & Completion and Providing DOT

Pre-visit session with an interpreter

Encourage the interpreter to:

- Speak in first person (as though they are the client while they speak the client's words)
- Not to offer opinions
- Encourage the client to speak directly to the provider
- Check for understanding frequently throughout the visit
- Request that the client pause often

Using a trained medical interpreter is best. If you must use an untrained interpreter:

- Request that the interpreter ask for clarification before changing any words or phrases that you or the client say
- Tell the interpreter where to position themselves
- Establish the context and the nature of the visit
- Determine any time constraints the interpreter may have
- **Stress confidentiality** [Only those who **need** to know have a **right** to know.]

An interpreter is acting as a cultural mediator assisting us in traversing various cultural bumps that may emerge in our work with non-English speaking clients. The interpreters can increase awareness of cultural bumps that lead to misunderstanding, for example:

- Content: what is said or done,
- Process: how it is said or done and
- Culture based misunderstandings: avoid stereotypes.

Interpreters are there to assist in identifying any U.S. cultural norms or biomedical norms and practices that may clash with those of the client's culture. They stand with one foot in each world.

With the client

While working with any client it is important to follow their non-verbal expressions. It is especially important with clients from a culture different than your own. Their non-verbal expressions may convey important information about their culture/socialization. Pay close attention to the client's use of:

- personal space
- eye contact and feedback
- interruption and turn-taking
- gesturing
- facial expression
- silence
- dominance behaviors
- volume
- touching

Your verbal expressions need to be conveyed clearly, concisely and in an organized, caring manner. Simplify your language and avoid using jargon. **Ask the client to give you their understanding of their disease process, etc.** Make instructions and descriptions relevant to the

client. Highlight/underline key information that you want the client to absorb in pre-printed pamphlets.

Stress that all information shared will remain confidential. Encourage the client to speak directly to you or if at a clinic, directly to the medical provider. Encourage the client to pause for the translator and to use hand signals to better articulate their concerns/needs.

Facilitate a good interpreted session:

- Check for understanding among all parties
- Keep in mind that the interpreter is the medium, not the source of the message
- Beware of concepts that do not have linguistic or conceptual meaning in other languages/cultures.
- Avoid idiomatic speech, complicated sentence structure and sentence fragments
- Avoid asking several questions at the same time
- Encourage the interpreter to ask questions, to clarify and check for understanding
- Acknowledge the interpreter as a communication professional
- Be patient; interpreted sessions may be twice as long (schedule appropriate amount of time for appointment)
- Schedule an interpreter that is gender matched to the client if possible
- Age of the interpreter may also be of concern to some clients.

Spend time with the interpreter after the session to clarify information, review how the session went and make plans and adjustments as needed for future meetings.

Resources:

Definition of cultural competency - Maternal and Child Health Bureau (MCHB), Guidance for SPRANS Grant, Health Resources and Services Administration, U.S. Department of Health and Human Services, 1999.

Translation information – From “Improving Cross-Cultural Communication!” a lecture presented by Elaine Quinn, Refugee Health Screening Program, Texas Department of Health. August 2, 2001, Atlanta GA.

Tuberculosis Control Incentive Program ENROLLMENT FORM

AMERICAN LUNG ASSOCIATION® of Wisconsin

Agency name: _____

Agency address: _____

_____

_____

Health Officer: _____

Tuberculosis Control Program Contact: _____

- We understand that we will receive a $100 program start-up check to serve as a base for our Tuberculosis Control Incentive Program account.
- As a participant in the American Lung Association's Tuberculosis Control Incentive Program we agree to spend funds made available through the program only to provide incentives/enablers to tuberculosis clients.
- We agree to submit purchase receipts and completed purchase logs and disbursement records to the American Lung Association of Wisconsin to verify incentive purchases and distribution.
- We understand that we may submit purchase receipts, purchase logs and disbursement records, along with a completed *reimbursement request* to receive reimbursement *at any time*.
- We agree to return the $100 Tuberculosis Control Incentive Program account base to the American Lung Association of Wisconsin if and when we should decide to discontinue participation in the Tuberculosis Control Incentive Program.

Health Officer Signature: _____ **Date:**_____

Tuberculosis Control Program Contact Signature: _____ **Date:**_____

Please Return to: American Lung Association of Wisconsin,
150 S. Sunny Slope Road, Suite 105, Brookfield, WI 53005-4857

Tuberculosis Control Incentive Program PURCHASE LOG

AMERICAN LUNG ASSOCIATION® of Wisconsin

Each time incentives are purchased for client distribution this log must be completed and signed by the purchaser. Please attach all the receipts for purchases to the log.

Agency Name: _____

Telephone: _____ **Date Submitted:** _____

Date	Description of Items Purchased	Signature of Purchaser	Amount Spent

TOTAL SPENT: _____

Please Return to: American Lung Association of Wisconsin,
150 S. Sunny Slope Road, Suite 105, Brookfield, WI 53005-4857

AMERICAN LUNG ASSOCIATION® of Wisconsin

Tuberculosis Control Incentive Program
DISBURSEMENT RECORD

Agency Name: _____

Telephone: _____ Date Submitted: _____

Date	Confidential Client Identification (*Name, Initials or ID Number assigned by State TB Program)*	Client Date of Birth	TB Type		Incentive Used	Value/ Approximate Value
			Suspect or Active	Latent		

Please Return to: American Lung Association of Wisconsin, 150 S. Sunny Slope Road, Suite 105, Brookfield, WI 53005-4857

Tuberculosis Control Incentive Program
REIMBURSEMENT REQUEST

AMERICAN LUNG ASSOCIATION of Wisconsin

Make check payable to: _____

Mail check to the attention of: _____

Agency name: _____

Address to which the check should be mailed: _____

_____

_____

_____

Total reimbursement amount requested: _____

Signature: _____

Date: _____

Please Return to: American Lung Association of Wisconsin,
150 S. Sunny Slope Road, Suite 105, Brookfield, WI 53005-4857